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EXAMINER	
CHIN, C	

ART UNIT	PAPER NUMBER
1641	4

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 11/2/97
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-41 is/are pending in the application.
- Of the above, claim(s) 22-41 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-21 is/are rejected.
- ☒ Claim(s) 2-3, 10-14, & 20-21 is/are objected to.
- ☒ Claims 1-41 are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I - claims 1-21 in Paper No. 3 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

2. The drawings are objected to for the reasons set forth in the attached PTO-948. Correction is required.

Claim Rejections - 35 U.S.C. § 112

3. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague. The recitation of "operatively associated" in part (f) is clear as to how the lower support layer is related to the upper support layer.

Claim Rejections - 35 U.S.C. § 102

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Krause et al.

Krause et al (U.S. Patent 5,284,622) discloses a device for detection of analytes. The device comprises a base body (4) with a trough-shaped depression (6) in which resides a multilayered test element. The test element is composed of layers (7), (8), and (9) lying loosely on one another. Layer (7) is an erythrocyte separation layer (i.e. a filter layer). Layer (8) may be a paper layer impregnated with a reagent for a preliminary reaction, while there may be used as the bottommost layer for example a reagent film which contains a reagent system which serves for a color change characteristic of the analysis on the underside of layer (9) designated as the color formation layer. A retaining net (13) lies on top of layer (7) and is bonded to base body (4). Retaining net (13) can function as a spreading layer to uniformly distribute sample liquid to layer (7) (see Fig. 2 and col. 4, lines 30-68).

The top face of base body (4) reads on the upper support layer of the instant device where in the upper portion of the trough-shaped depression (6) is a sample receiving port. The base body (4) itself functions as a means for retaining fluid sample since it is a solid composition that will

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hold a fluid sample. The bottom face of base body (4) reads on the lower support layer of the instant device with an opening (14) to view assay results on the bottom side of layer (9).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5-9 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krause et al in view of Allen et al.

See above for the teachings of Krause et al.

Krause et al differ from the instant invention in failing to teach the use of red blood cell binding agent, such as a lectin, in filter layer (7).

Allen et al (U.S. Patent 4,987,085) discloses a multilayered device for analyzing blood samples. The device includes a separation membrane which contains a red blood cell binding reagent, such as lectins and antibodies (col. 3, lines 13-29). The device also includes a reagent layer that can contain reagents for the detection of analytes in a blood sample including cholesterol and glucose (col. 6, lines 28-68).

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It would have been obvious to one of ordinary skill in the art to incorporate a red blood cell binding agent, such as lectins, as taught by Allen et al in the filter layer (7) of the device of Krause et al because the presence of a red blood cell binding agent in the filter layer (7) would enhance the ability of the filter layer (7) to remove red blood cells from a blood sample that is being assayed.

With respect to claims 5, 8, 9, and 15-19, it would have been obvious to one of ordinary skill in the art to incorporate the specific reagent solutions recited in claims 5, 8, 9, and 15-19 in the device of Krause et al because the choice of analyte dictates what reagents would be required. The device of Krause et al is generic with respect to the types of analytes that can be detected. For example, if the one of ordinary skill in the art were to use the device of Krause et al for the detection of glucose, then reagents for the detection of glucose would be incorporated into the device of Krause et al.

Allowable Subject Matter

8. Claims 2-3, 10-14, and 20-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
February 1, 1999

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800 / 641